K022423
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510(k) Summary

Date
July 17, 2002

Submitter
RIGID FX Orthopedics, Inc
3601 South Congress Ave.
Bldg B, Suite 300
Austin, TX 78704

SEP 17 2002

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-4694

Common name
External Fixation Frame Component

Classification name
Single/multiple component metallic bone fixation appliances and accessories (per 21 CFR section 888.3030)

Equivalent Device

Device	Company/510(k)	Description	Intended Use
Hoffman II Hybrid Frame System	Howmedica Osteonics/ K000957	Carbon fiber rings to receive various pin clamps and distractors	*see below
Ilizarov External Fixation System	Smith & Nephew	Aluminum and carbon fiber rings to receive various pin clamps and distractors	*see below
TrueLok	Encore Medical, L.P./ K941048	Aluminum rings to receive various pin clamps and distractors	*see below
Taylor Spatial Frame External Fixation System	Smith & Nephew/K970748	Carbon fiber rings to receive various pin clamps and distractors	*see below

Device Description
This device is the ring component of an external fixation device. Pin/wire clamps and distractors are attached to the ring to complete a rigid construct utilized to stabilize long bone fractures or in limb lengthening or correction of bony deformities. These rings are fabricated from two beryllium-aluminum alloy rings encased in an injection-molded polycarbonate plastic.

Intended Use
When used with other components this device stabilizes open and/or unstable fractures of long bones including intracapsular, intertrochanteric, supracondylar, or condylar. It is also used for joint fusions and limb lengthening of deformity corrections which involve cutting the bone.

Summary of Technological Characteristics Compared to Predicate Device
Material of this device is beryllium-aluminum alloy other devices are fabricated from aluminum alloy or carbon fiber composite.

Summary Nonclinical Tests
This device has similar load carrying capabilities as solid rings made of aluminum alloy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2002

Rigid RX Orthopedics, Inc.
J. D. Webb
c/o J. D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K022423
Trade/Device Name: External Fixation Ring
Regulation Number: 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: July 17, 2002
Received: July 24, 2002

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

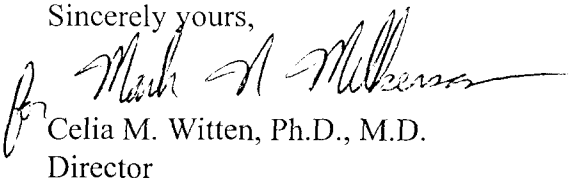
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) number (if known): K022423

Device Name: External Fixation Ring

Indications for Use:

External Fixation Ring
Indications for Use

When used with other components this device stabilizes open and/or unstable fractures of long bones including intracapsular, intertrochanteric, supracondylar, or condylar. It is also used for joint fusions and limb lengthening of deformity corrections which involve cutting the bone.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(Optional format 1-2-96) _____

(Division Sign-off)
Division of General, Neurological
and Restorative Devices

510(k) Number _____

for Mark A. Miller

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022423